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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/568,704

02/16/2006

Karlheinz Bortlik

112701706

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EXAMINER

MI, QIUWEN

ART UNIT

PAPER NUMBER

1655

NOTIFICATION DATE

DELIVERY MODE

07/07/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

<b>Office Action Summary</b>	<b>Application No.</b> 10/568,704	<b>Applicant(s)</b> BORTLIK ET AL.	
	<b>Examiner</b> QIUWEN MI	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) 6-8, 12, 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 9-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's amendment in the reply filed on 5/12/08 is acknowledged. Claim 13 is cancelled. Claims 1-12, 14, and 15 are pending. Claims 6-8, 12, 14, and 15 are withdrawn as they are directed toward a non-elected invention group. **Claims 1-5, and 9-11 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

### **CONTINUED EXAMINATIONS**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/11/08 has been entered.

### **Claim Rejections –35 USC § 112, 2<sup>nd</sup>**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, and 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially free" in claims 1, and 9-11 is a relative term which renders the claim indefinite. The term "substantially free " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For instance, "substantially free" could be construed as containing less than 0.1% of fiber and other insoluble compounds; or containing less than 10% of fiber and other insoluble compound.

Claim 9 recites "UV" in line 2, and Applicant is required to spell out the full name of "UV".

Therefore, the metes and bounds of claims are rendered vague and indefinite. The lack of clarity renders the claims very confusing and ambiguous since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

### **Claim Rejections –35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bortlik et al (US 2002/0107292), in view of Zelkha et al (US 5,837,311).

Bortlik et al disclose a cosmetic composition, milk for the face (water soluble at room temperature), comprising 2% powder according to Example 1 (containing whey protein isolate, lycopene, and oleoresin (lipid, contains resin acid, see Wikipedia online) [0050]), 0.4% carboxyvinyl polymer (polysaccharides), 3% soybean protein, and reminder being water [0059]. Bortlik et al teach that the invention relates to methods of forming the primary composition, the food supplement, cosmetic preparation or pharmaceutical preparation containing the same, and to a method for protecting skin tissue against ageing by administering to a subject in need of such protection one of the primary, oral, or cosmetic compositions disclosed herein [0008]. Bortlik et al further teach that the composition can be provided in the form of a powder (pulverulent), liquid or gel [0015], the composition can additionally comprise vitamin E and vitamin C (ascorbic acid, organic acid) [0018]. At last, Bortlik et al teach that the composition enhance the bioavailability of the lipophilic bioactive compound in the body and to slow down the aging of the skin [0023].

Bortlik et al do not teach the concentrate is substantially free of fibers and other insoluble compounds, or the exact claimed amount of the components in the composition.

Zelkha et al teach the lycopene extract (thus a concentrate) is separated from the pulp, preferably by means of a continuous decanter, and is then filtered. Preferably, the filtration is in

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two stages, a crude one and a fine one, to ensure the removal of even the very fine particles of pulp (thus substantially free of fiber). The last fiber preferably has a mesh size of 2 micron (thus substantially free of other insoluble compounds) (col 7, lines 55-62). Zelkha et al also teach that the tomato oleoresin contains a high concentration of lycopene, which can be used as a natural coloring material, e.g., in beverages, drinks, foodstuffs, cosmetics, etc (col 6, lines 7-13). Zelkha et al further teach that the invention provides a process for the production of lycopene-containing oleoresin from tomatoes in the most efficient manner, in particular for obtaining oleoresin having an optimal combination of high lycopene content and lycopene stability (col 2, lines 8-14).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the inventions of Bortlik et al since Bortlik et al teach that the composition enhance the bioavailability of the lipophilic bioactive compound in the body and to slow down the aging of the skin.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the filtration steps of Zelkha et al to remove pulp (fiber) and other insoluble compounds since Zelkha et al that the process provides the production of lycopene-containing oleoresin from tomatoes in the most efficient manner, in particular for obtaining oleoresin having an optimal combination of high lycopene content and lycopene stability.

Since both of the inventions yielded beneficial results in food and cosmetic industry, one of ordinary skill in the art would have been motivated to make the modifications. Regarding the limitation to the amount of the components in the composition, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that “*Bortlik* fails to disclose or suggest a natural lycopene concentrate, wherein the concentrate is substantially free of fibers and other insoluble compounds as required, in part, by the present claims...At no place in the disclosure does *Bortlik* disclose or even suggest that any fibers or insoluble compounds from the primary composition are filtered out or removed. In fact, the primary composition of *Bortlik* has a relatively high ratio of carrier-active compound. See, *Bortlik*, [0020]. As such, the primary composition of *Bortlik* provides a process that requires organic solvents and has less stability than the presently claimed concentrate” (page 6, 2<sup>nd</sup> paragraph). Applicant further argues that “Therefore, because *Bortlik*, fails to disclose or suggest a natural lycopene concentrate obtained without the use of solvents, wherein the concentrate is substantially free of fibers and insoluble compounds as is required, in part, by the claims, *Bortlik* fails to render obvious the present claims. For at least these reasons, Applicants respectfully submit that *Bortlik* does not render obvious Claims 1-5 and 9-11” (page 6, 3<sup>rd</sup> paragraph).

Applicant’s arguments with regard to *Bortlik* does not teach the concentrate is substantially free of fibers and other insoluble compounds have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Zelkha et al. Applicant’s argument regarding

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Bortlik fails to disclose a natural lycopene concentrate obtained without the use of solvents is not persuasive, as "without the use of solvents" is not in the claim language.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejection is maintained.

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### **Conclusion**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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QM

/Michele Flood/

Primary Examiner, Art Unit 1655